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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,871	09/28/2001	Alan S. Kopin	00398/512002	4950

21559 7590 05/28/2004

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EXAMINER	
ULM, JOHN D	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,871	KOPIN ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *10-13 and 23-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,14-22,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/02/04, 06/17/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1 to 36 are pending in the instant application.

2) Claims 10 to 13 and 23 to 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species of receptor and/or G protein, there being no allowable generic or linking claim. Election was made **without** traverse in the correspondence filed 18 March of 2004. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3) The instant specification does not comply with 37 C.F.R. § 1.84(U)(1), which states that partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Figure 1 of the instant application, for example, is presented on fifteen separate panels. The fifteen sheets of drawings which are labeled " Figure 1" in the instant specification should be renumbered "Figures 1A to 1O", respectively. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification accordingly.

4) The drawings in the instant application do not comply with 37 C.F.R. § 1.821(d), which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. M.P.E.P. 2422.02 expressly states that "when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing,

the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings". The instant specification does not comply because the description of Figure 1, for example, refers to "SEQ ID NOS:2-75 without indicating which of the plurality of sequences presented in the figure correspond to a particular sequence identifier. Figures 12 and 13 suffer from a similar deficiency. Correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5) Claims 1 to 9, 14 to 22, 35 and 36 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Claim 1 is expressly directed to a method of identifying a receptor having "altered signaling". The limitation "altered signaling" requires a point of reference and none is provided by the claim. If the invention is intended to be a method of identifying a form of a polymorphic receptor protein in which signaling activity is different from a referenced form of that receptor, then a comparison step is required for operability. One can not determine if a measured property is different (altered) unless one is comparing that property to a reference property which that measured property is different from.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6) Claims 1 to 9, 14 to 22, 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant specification does not provide the guidance needed to determine if a polymorphic receptor has "altered signaling" without employing a comparative step, essentially for those reasons given above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7) Claims 1 to 9, 14 to 22, 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7.1) Claims 1 to 9 and 14 to 22 are vague and indefinite because the limitation "altered" requires a point of reference and none is given.

7.2) Claim 4 is vague and indefinite because the limitations "increase" and "decrease" each require a point of reference and none is given.

7.3) Claims 5 and 6 are vague and indefinite because the limitations "increased" and "decreased" each requires a point of reference and none is given.

7.4) Claim 14 is vague and indefinite because the limitation "alteration" point of reference and none is given.

7.5) Claim 15 is vague and indefinite because the term "ligand induced response" is not a proper antecedent basis for the limitation "said ligand".

7.6) Claims 35 and 36 are vague and indefinite because the limitation "decreased" requires a point of reference and none is given.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8) Claims 1 to 3, 5, 6, 8, 9, 14 to 21 and 35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Montmayeur et al. publication (P.N.A.S. 88:3135-3139, Apr. 1991). The assays that were described in Figures 2 and 3 of the Montmayeur et al. publication are fully encompassed by the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9) Claims 4, 7, 22 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montmayeur et al. publication (P.N.A.S. 88:3135-3139, Apr. 1991), as applied to claims 1 to 3, 5, 6, 8, 9, 14 to 21 and 35 under 35 U.S.C. 102(b) above. These claims distinguish over claims 1 to 3, 5, 6, 8, 9, 14 to 21 and 35 in requiring the receptor being evaluated to have increased or decreased basal activity, including the absence thereof. The Montmayeur et al. publication shows that it was a routine practice in the art, prior to the time of the instant invention, to compare the functional properties of any two or more alternative structural forms of a gene product, or mutants thereof, to gain an understanding of the effects of specific structural differences upon functional differences and thereby assign critical protein functions to the structures associated

therewith. An artisan, therefore, would have found it prima facie obvious to have applied the analytical method of Montmayeur et al. publication to any form of a D2 dopamine receptor irrespective of its actual biological activity relative to those which had been previously characterized.

10) Claims 1 to 9, 14 to 22, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Kopin et al. patent (5,750,353, cited by Applicant) in view of the Jinsi-Parimoo et al. publication (Endocrinology 138(4):1471-1475, Apr. 1997). The text beginning in the third paragraph in column 12 of Kopin et al. described human CCK-A receptor and taught the production of intentionally modified mutants thereof. This reference disclosed an assay for quantitating the activity of wild-type and mutant CCK-A receptors by measuring inositol phosphate production in COS cells expressing those receptors and comparing the values obtained thereby. The Kopin et al. patent does not anticipate the instant claims because it did not employ a reporter gene to measure receptor activity.

The abstract of the Jinsi-Parimoo et al. publication described a process for measuring the activity of "a G protein-coupled receptor that signals via the phosphoinositide transduction pathway" by "using a protein kinase C-responsive reporter gene" instead of measuring the formation of inositol phosphate second messenger molecules. This reference expressly described the reporter gene system as a "more sensitive system" than one that measures the formation of inositol phosphate second messenger molecules such as the method that was employed by Kopin et al. One of ordinary skill in the are of receptor biology would have found it *prima facie*

obvious to have employed the reporter system of Jinsi-Parimoo et al. in place of the method of measuring inositol phosphate production employed by Kopin et al. to measure the functional differences between different forms of CCK-A receptors simply because the Jinsi-Parimoo et al. expressly taught that the reporter system described therein was more sensitive than the measuring system employed by Kopin et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kunz Gary can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1800